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DRINKER BIDDLE & REATH (DC) 1500 K STREET, N.W. SUITE 1100 WASHINGTON, DC 20005-1209			LILLING, HERBERT J	
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Please find below and/or attached an Office communication concerning this application or proceeding.

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In re Application of :
Sumida et al. :
Serial No.: 10/527,703 : DECISION ON PETITION
Filed: 13 October 2005 :
Attorney Docket No.: 47259-0528-00-US(216939) :

This letter is in response to the Petition under 37 C.F.R. 1.144 filed on 7 December 2009.

BACKGROUND

This application was filed as a national stage application in compliance with 35 USC 371 and as such is subject to PCT unity of invention rules.

The examiner mailed a lack of unity determination on 8 November 2007 which divided the original claims 1-30 into ten groups. An election of species was also required.

On 29 November 2007, the examiner sent applicants a miscellaneous communication which corrected typographical errors in the lack of unity determination.

On 2 May 2008, Applicants elected Group II, with traverse.

Applicants elect the following species with traverse. For part A (product produced), Applicants elect (a) arachidonic acid), (b) omega 6 series PUFA: arachidonic acid, and (c) omega 9 series PUFA: MEAD acid) with traverse. For part B, Applicants elect palm oil with traverse. And for part C, Applicants elect the 1,3 position specific lipase produced by *Rhisopus Delmar*. Claims that read on the elected species are claims 10-14.

On 3 July 2008, the examiner sent applicants a notice of non-compliant response acknowledge the election of Group II, but still requiring an election of Species A.

On 4 August 2009, applicant elected with traverse for Species A:

A transesterified triglyceride containing at least 20% arachidonic acid, obtained by the process according to claim 1, which contains at least 40% of triglycerides with one residue of arachidonic acid in the molecule and/or no more than 4.0% of a triglyceride with 3 residues of arachidonic acid in the molecule.

Claims 10 and 14 read on the elected species.

On 5 June 2009, the examiner acknowledged the election of Group II, claims 10-16 and election of species which included Claims 10 and 14. The examiner considered the traversal and made the restriction requirement FINAL. Claims 1-9, 11-13, 15-30 were withdrawn from consideration as being directed to non-elected invention.

Claims 10 and 14 were rejected under 35 USC 102(b) as being anticipated by five separate articles.

Claims 10 and 14 were rejected under 35 USC 103(a) as being unpatentable over combinations of the five separate articles applied under 35 USC 102(b).

On 11 June 2009 and 20 July 2009, applicants filed two Information Disclosure Statements.

On 23 October 2009, the examiner prepared a telephonic interview summary indicating that the notice of non-compliant amendment dated 3 July 2008 has been vacated. The examiner indicated that an amended claim drawn only to a product and not a product by process claim would initiate new issues. The examiner also indicated that an amended process claim would most likely be allowable over the prior art, and that the applicant would be allowed to change election prior to a final office action to expedite possible allowance, whereas the proposed amended product claim lacks an enabling disclosure to the structure of the claimed products.

On 7 December 2009, applicants filed a response to the Office action, an Information Disclosure Statement and this petition under consideration.

DISCUSSION

The petition and file history have been carefully considered.

This national stage filing is entitled to PCT Unity of Invention practice with regard to any restriction or election of species requirement. However, the examination of a national stage filing must comport with US practice per 35 USC 372(a),

All questions of substance and, within the scope of the requirements of the treaty and Regulations, procedure in an international application designating the United States shall be determined as in the case of national applications regularly filed in the Patent and Trademark Office.

Before turning to the merits of the petition, one item is noted and hereby corrected in the prosecution history to help provide a clear record per by MPEP 814, which states:

The examiner must provide a clear and detailed record of the restriction requirement to provide a clear demarcation between restricted inventions so that it can be determined whether inventions claimed in a continuing application are consonant with the restriction requirement and therefore subject to the prohibition against double patenting rejections under 35 U.S.C. 121. Geneva Pharms. Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1381, 68 USPQ2d 1865, 1871 (Fed. Cir. 2003). See also MPEP § 804.01.

The restriction requirement mailed 8 November 2007 indicated that process claim 22 would be examined with Group II. Because Claim 22 shares the same or corresponding technical feature with Claims 1-9 and 21, it should have been grouped with the process claims.

Turning now to the merits of the petition, applicants requests that

- (1) rejoinder of claim 11 for further examination on the merits with claim 14
- (2) re-organization of the Groups into Group I, Claims 1-9 and 21-23 and Group II, claims 11-16 and 27-30
- (3) revision of the PAIR entry to 3 July 2008 to reflect the vacated Notice of Non-Responsive Amendment
- (4) the Office provide full translations of the references relied upon for rejection under 35 USC 102 and 103.

(1) Rejoinder of Claim 11 with Claim 14.

Examined Claim 10 was drafted in product by process format. MPEP 2173/05(p) provides the following guidance on product by process claims:

A product-by-process claim, which is a product claim that defines the claimed product in terms of the process by which it is made, is proper. *In re Luck*, 476 F.2d 650, 177 USPQ 523 (CCPA 1973); *In re Pilkington*, 411 F.2d 1345, 162 USPQ 145 (CCPA 1969); *In re Steppan*, 394 F.2d 1013, 156 USPQ 143 (CCPA 1967)....An applicant may present

claims of varying scope even if it is necessary to describe the claimed product in product-by-process terms. Ex parte Pantzer, 176 USPQ 141 (Bd. App. 1972).

In the interview summary dated 23 October 2009, instead of the substance of the claims, the examiner appears to be relying upon the format of withdrawn product claim 11 to maintain division from the examined product by process claim 10. The amendment dated 7 December 2009 cancelled claim 10 and re-wrote claim 11 in independent form.

Claim 11. (Withdrawn – Currently Amended): A transesterified oil/fat or triglyceride which is an oil/fat or triglyceride containing at least 20% of polyunsaturated fatty acids containing 20 or more carbons and two or more double bonds, obtained by a production process according to claim 1, and which contains at least 40% of triglycerides with one residue of a polyunsaturated fatty [[acids]] acid containing 20 or more carbons and two or more double bonds in the molecule, and/or and no more than 4.0% of triglycerides with 3 residues of the same polyunsaturated fatty [[acids]] acid containing 20 or more carbons and two or more double bonds.

Moreover, in the amendment filed 7 December 2009, elected and examined claim 14 has been made dependent upon generic claim 11.

Claim 14. (Currently Amended): [[A]] The transesterified oil/fat or triglyceride according to claim 11, containing at least 20% of arachidonic acid, obtained by a production process according to claim 1, and which contains at least 40% of triglycerides with one residue of arachidonic acid in the molecule and/or and no more than 4.0% of AAA, wherein AAA is a triglyceride with 3 residues of arachidonic acid in the molecule.

The examiner has required an election of species amongst the types of PUFA in claims 12, 13, 14, 15, and 16. In the latest amendment, claims 12-16 dependent directly upon claim 11. As such, amended claim 11 can now be considered a linking claim, which encompasses and links the species of claims 12-16. MPEP 809 requires that generic claims must be examined with the elected invention/species. See final emphasized sentence below:

The most common types of linking claims which, if allowable, act to prevent restriction between inventions that can otherwise be shown to be divisible, are

- (A) genus claims linking species claims; and
- (B) subcombination claims linking plural combinations.

Where an application includes claims to distinct inventions as well as linking claims, restriction can nevertheless be required.

The linking claims must be examined with, and thus are considered part of, the invention elected.

For these reasons, generic claim 11 and elected species claim 14 will be examined together.

(2) Re-organization of the Groups.

Applicants request that Groups I-X be re-organized into two groups as follows:

Group I, Claims 1-9 and 21-23, drawn to the processes

Group II, claims 11-16 and 27-30, drawn to the product.

Upon review of the originally filed claims, Claims 10-16, which are written in product by process fashion, were placed in separate groups from the product claims 17-26. This is incorrect. A product defined by the process by which it can be made is still a product claim (*In re Bridgeford*, 357 F.2d 679, 149 USPQ 55 (CCPA 1966)). For this reason, in the original unity of invention determination, claims 10-16 and 17-26 should have been grouped together as sharing the same or corresponding technical feature of trans-esterified oil/fat or triglycerides. (Claims 17-20 are cancelled in the latest amendment.)

Applicants elected the product trans-esterified oil/fat or triglycerides and species of arachidonic acid. A complete Office action on the merits would have then addressed claims 10, 11, 14 and 18, all of which are limited to or encompass trans-esterified oil/fat or triglycerides containing arachidonic acid. Compare examined claim 14 with withdrawn claim 18 below. Because the Office only addressed claims 10 and 14 on the merits in the first Office action, it is considered incomplete for not addressing claims 11 and 18.

14. (Currently Amended) A transesterified oil/fat or triglyceride containing at least 20% of arachidonic acid, obtained by a production process according to claim 1, any one of claims 1 to 9, and which contains at least 40% of triglycerides with one residue of arachidonic acid in the molecule and/or no more than 4.0% of AAA, wherein AAA is [(i)] a triglyceride with 3 residues of arachidonic acid in the molecule[(i)].

18. (Original) An oil/fat or triglyceride containing at least 20% of arachidonic acid, and which contains at least 40% of triglycerides with one residue of arachidonic acid in the molecule and/or no more than 4.0% of AAA.

Claims 27-30 are directed to nutritive and food compositions comprising the trans-esterified oil/fat or triglycerides. Because these product claims require the same or corresponding technical feature as their dependent claims 10-26, they should be grouped together. This would be consistent with Example 13 in Chapter 10 of the International Search and Examination Guidelines which states:

“Claim 1: Filament A for a lamp.

Claim 2: Lamp B having filament A.

Claim 3: Searchlight provided with lamp B having filament A and a swivel arrangement C.

Unity exists between claims 1, 2, and 3. The special technical feature common to all the claims is the filament A.”

For these reasons, the product claims are grouped together as Group II and the process claims are grouped together as Group I. The lack of unity determination between the Group II product and Group I process inventions is contingent upon the prior art teaching the same or corresponding technical feature of the product. See also MPEP 1893.05(d) which states in part:

If an examiner (1) determines that the claims lack unity of invention and (2) requires election of a single invention, when all of the claims drawn to the elected invention are allowable (i.e., meet the requirements of 35 U.S.C. 101, 102, 103 and 112), the nonelected invention(s) should be considered for rejoinder. Any nonelected product claim that requires all the limitations of an allowable product claim, and any nonelected process claim that requires all the limitations of an allowable process claim, should be rejoined. See MPEP § 821.04. Any nonelected processes of making and/or using an allowable product should be considered for rejoinder. The examiner should notify applicants of potential rejoinder of non-elected process claims by placing form paragraph 8.21.04 at the end of any lack of unity determination made between a product and a process of making the product or between a product and a process of using the product.

(3) Revision of the PAIR entry to 3 July 2008

Applicants' request that the PAIR entry for 3 July 2008 be corrected to reflect the vacated Notice of Non-Responsive Amendment has been forwarded to the technical support staff.

(4) Request for Full translations of the references.

Full machine-generated translations of the three references were scanned into the file on 20 January 2010.

DECISION

The petition is **GRANTED** for the reasons set forth above.

The restriction requirement between Groups I-X has been re-organized into two groups as follows:

Group I, Claims 1-9 and 21-23, drawn to the processes
Group II, claims 11-16 and 27-30, drawn to the product.

The election of species made between types of PUFAs recited in dependent claims 12-16 has been maintained, pending allowability of the independent generic claim. Claims 11, 14, 27-30 are under examination because they either recite or encompass the elected species.

The lack of unity determination between the elected product Group II and the non-elected process of Group I may be maintained as long as the technical feature of the product does not make a contribution over the prior art. Should the elected product be found free of the prior art, unity of invention should be reconsidered and non-elected process claims rejoined. See MPEP 1893.05(d) and 821.04(b).

The Office action mailed 5 June 2009 has been withdrawn as incomplete for not having addressed claims 11 and 18.

The application will be forwarded to the examiner for consideration of the Information Disclosure Statements, the papers filed 7 December 2009 and for preparation of an Office action consistent with this decision. Should the generic claims become allowable, the examiner should withdraw the election of species per MPEP 809 and MPEP 821.04(a). Should the elected product claims become allowable, the examiner should follow rejoinder practice in MPEP 821.04(b).

Should there be any questions about this decision, please contact Quality Assurance Specialist Julie Burke, by letter addressed to Director, Technology Center 1600, at the address listed above, or by telephone at 571-272-0512 or by facsimile sent to the general Office facsimile number, 571-273-8300.


Remy Yucel
Director, Technology Center 1600